

REMARKS/ARGUMENTS

Claims 1, 14, 21 and 22 have been amended and Claims 10 and 19 have been canceled by this Amendment. Accordingly, Claims 1-9, 11-18 and 20-28 are now pending in this application.

In the Office Action of January 11, 2004, the Examiner has maintained the rejection of Claims 1-28 of the above-referenced application for double patenting over Claims 1-28 of U.S. Patent No. 5,164,796 (the "796 Patent"). As stated above, Claims 10 and 19 have been canceled. Applicants respectfully request reconsideration and withdrawal of this rejection as to pending Claims 1-9, 11-18 and 20-28.

The Examiner maintains that the pending claims are not patentably distinct from the claims of the 796 Patent because "both inventions claim a device or instrument for detecting or monitoring the growth of microorganisms in a specimen comprising (a) a container; (b) a filter or means for filtering; and a sensor means." The Examiner further asserts that "[b]oth inventions require culturing of the microbial specimen before detecting or monitoring microbial growth with the device or instrument claimed." The Examiner also asserts that "the structural features claimed in both inventions are substantially identical or describe minor variations deemed obvious to one having ordinary skill in this art at the time this invention was made."

Applicants respectfully reassert that the present claims are patentably distinct from the claims of the 796 Patent. First, the claims of the 796 Patent do not provide for a device having a (1) an inlet and an outlet in fluid communication with the chamber as

required by the present claims; and (2) a filter means as required by the present claims. The claims of the 796 Patent require the presence of a sealable, sterilizable container. See the 796 Patent at column 10, lines 7-39. The container is further provided in the specification of the 796 Patent as being a sealed container. See the 796 Patent at column 2, lines 36-39 and column 3, lines 48-49. The container does not have any inlets or outlets for the specimen to flow into and out of the container, rather, the specimen is housed in the container for incubation. See the 796 Patent at column 3, lines 46-49.

The present invention, though, requires a container defining a chamber therein and having an inlet and an outlet in fluid communication with the chamber. See the present application at page 2, lines 9-11. A specimen is passed into the chamber through the inlet and out of the chamber through the outlet. See the present application at page 2, lines 14-16. The specimen is not housed nor cultured in the container.

With respect to the filter means required by the present claims, the Examiner asserted in the Office Action of October 1, 2003 that the invention of the 796 Patent selectively uses semi-permeable membranes or compositions which operatively filter the fluid sample and encompasses the instant invention as claimed. The semi-permeable membranes in the invention of the 796 Patent are a part of the sensor. See the 796 Patent at column 3, lines 52-55. Likewise, the present invention includes a sensor including semi-permeable membranes. The sensor in the invention in the 796 Patent and in the presently claimed device do not filter fluids, but rather, are used to determine the presence of microorganisms by detecting or measuring changes in the pH of the specimen or the production of CO₂ within the specimen. See the 796 patent at column 2, lines 55-59. The

invention of the 796 Patent does not include a filter nor any component that filters fluids as required by the present claims.

Furthermore, it would not have been obvious to modify the invention of the 796 Patent to include an inlet, an outlet and a filter means as provided in the present invention since these components could not be operational in the invention claimed in the 796 Patent. It is an object of the 796 Patent to monitor pH or CO₂ changes in a specimen within a sealed container without entering the container during the monitoring process. See the 796 Patent at column 2, lines 36-39. Further, the claims of the 796 Patent require the specimen to be cultured in a culture medium and this medium enhances the production of certain microbial metabolic products. The monitoring process or incubation period for the specimen with the medium may last up to seven days before the population of organisms reaches a critical level or an increase in metabolic products can be measured. See the 796 Patent at column 4, lines 3-8.

The filter means of the present invention is mounted in the container between an inlet and an outlet at the end of the container opposite the sensor. The filter means filters fluids and collects the microorganisms as a specimen is passed into the inlet, through the filter means and out of the container through the outlet. If the inlet, outlet and filter means of the present invention were added to the container of the 796 Patent, a specimen could not be cultured in the sterile culture medium as required in the claims of the 796 Patent because the microorganisms in the specimen would be caught by the filter when the specimen is added to the container and the specimen would be passed out of the container through the outlet. As such, the instrument in the 796 Patent would not be operational as claimed if the inlet, outlet and filter means of the present invention were added to the instrument of the 796 Patent.

Therefore, it would not have been an obvious modification to add the inlet, outlet and filter means of the present invention to the instrument of the 796 Patent.

Second, the invention of the 796 Patent and the present invention do not both require culturing of the microbial specimen in the device or instrument claimed as asserted by the Examiner. In the invention of the 796 Patent, a specimen is added to the container and the specimen is cultured in the container for up to 7 days. The claims of 796 Patent require that the specimen is cultured in the container. See the independent claims of the 796 Patent at column 10, lines 9-12 and column 11, lines 54-59.

However, the present invention does not require or provide for culturing the microbial specimen in the device claimed. Rather, when a specimen is added to the present device, the microorganisms are caught in the filter and then cultured. In particular, the specimen is added to the presently claimed integrated device through the inlet, passed through the filter and out the device via the outlet. The microorganisms in the specimen are caught in the filter. The inlet and outlet can then be closed after a culture medium is added to culture the microorganisms caught in the filter. Accordingly, in the present invention, the specimen is not cultured in the container, rather only the microorganisms are cultured in the container whereas in the prior art, the whole specimen is cultured in the container.

Accordingly, Applicants respectfully submit that pending Claims 1-9, 11-18 and 20-28 are patentably distinct from the claims of the 796 Patent and this rejection should be withdrawn.

Also in the Office Action, the Examiner has maintained the rejection of Claims 1–21 of the above-referenced application for double patenting over Claims 1–21 of U.S. Patent No. 5,094,955 (the “955 Patent”). As stated above, Claims 10 and 19 have been canceled. Applicants respectfully request reconsideration and withdrawal of this rejection as to pending Claims 1-9, 11-18, 20 and 21.

The Examiner maintains that Claims 1-21 are not patentably distinct from Claims 1-21 of the 955 Patent because “both inventions claim a device or instrument for detecting or monitoring the growth of microorganisms in a specimen comprising (a) a container; (b) a filter or means for filtering; and a sensor means.” The Examiner further asserts that “[b]oth inventions require culturing of the microbial specimen before detecting or monitoring microbial growth with the device or instrument claimed.” The Examiner also asserts that “the structural features claimed in both inventions are substantially identical or describe minor variations deemed obvious to one having ordinary skill in this art at the time this invention was made.”

Applicants respectfully reassert that the present claims are patentably distinct from the claims of the 955 Patent. First, the claims of the 955 Patent do not provide for a device having a (1) an inlet and an outlet in fluid communication with the chamber as required by the present claims; and (2) a filter means as required by the present claims. The claims of the 955 Patent require the presence of a sealable specimen container in which the integrity of the container is not violated after sealing. See the 955 Patent at column 17, lines 30-45. The container is further provided in the specification of the 955 Patent as being a sealed container. See the 955 Patent at column 1, lines 10-14 and column 2, lines 31-36. The container does not have any inlets or outlets for the specimen to flow into and out of the

container, rather, the specimen is housed in the container for incubation. See the 955 Patent at column 2, lines 31-36.

The present invention, though, requires a container defining a chamber therein and having an inlet and an outlet in fluid communication with the chamber. See the present application at page 2, lines 9-11. A specimen is passed into the chamber through the inlet and out of the chamber through the outlet. See the present application at page 2, lines 14-16. The specimen is not housed nor cultured in the container.

With respect to the filter means required by the present claims, the Examiner asserted in the Office Action of October 1, 2003 that the invention of the 955 Patent selectively uses semi-permeable membranes or compositions which operatively filter the fluid sample and encompasses the instant invention as claimed. The semi-permeable membranes in the invention of the 955 Patent are a part of the sensor. See the 955 Patent at column 3, line 66 through column 4, line 1. Likewise, the present invention includes a sensor including semi-permeable membranes. The sensor in the invention in the 955 Patent and in the presently claimed device do not filter fluids, but rather, are used to determine the presence of microorganisms by detecting or measuring changes in the pH of the specimen or the production of CO₂ within the specimen. See the 955 patent at column 2, lines 36-41. The invention of the 955 Patent does not include a filter nor any component that filters fluids as required by the present claims.

Furthermore, it would not have been obvious to modify the invention of the 955 Patent to include an inlet, an outlet and a filter means as provided in the present invention since these components could not be operational in the invention claimed in the 955 Patent.

It is an object of the 955 Patent to monitor pH or CO₂ changes in a specimen within a sealed container without entering the container during the monitoring process. See the 955 Patent at column 1, lines 10-14. Further, the claims of the 955 Patent require the specimen to be cultured in a culture medium and this medium enhances the production of certain microbial metabolic products. The monitoring process or incubation period for the specimen with the medium may last up to seven days before the population of organisms reaches a critical level or an increase in metabolic products can be measured. See the 955 Patent at column 4, lines 56-61.

The filter means of the present invention is mounted in the container between an inlet and an outlet at the end of the container opposite the sensor. The filter means filters fluids and collects the microorganisms as a specimen is passed into the inlet, through the filter means and out of the container through the outlet. If the inlet, outlet and filter means of the present invention were added to the container of the 955 Patent, a specimen could not be cultured in the sterile culture medium as required in the claims of the 955 Patent because the microorganisms in the specimen would be caught by the filter when the specimen is added to the container and the specimen would be passed out of the container through the outlet. As such, the instrument in the 955 Patent would not be operational as claimed if the inlet, outlet and filter means of the present invention were added to the instrument of the 955 Patent. Therefore, it would not have been an obvious modification to add the inlet, outlet and filter means of the present invention to the instrument of the 955 Patent.

Second, the invention of the 955 Patent and the present invention do not both require culturing of the microbial specimen in the device or instrument claimed as asserted by the Examiner. In the invention of the 955 Patent, a specimen is added to the container and

the specimen is cultured in the container for up to 7 days. The claims of 955 Patent require that the specimen is cultured in the container. See the independent claims of the 955 Patent at column 17, lines 32-34.

However, the present invention does not require or provide for culturing the microbial specimen in the device claimed. Rather, when a specimen is added to the present device, the microorganisms are caught in the filter and then cultured. In particular, the specimen is added to the presently claimed integrated device through the inlet, passed through the filter and out the device via the outlet. The microorganisms in the specimen are caught in the filter. The inlet and outlet can then be closed after a culture medium is added to culture the microorganisms caught in the filter. Accordingly, in the present invention, the specimen is not cultured in the container, rather only the microorganisms are cultured in the container whereas in the prior art, the whole specimen is cultured in the container.

Accordingly, Applicants respectfully submit that pending Claims 1-9, 11-18 and 20-28 are patentably distinct from the claims of the 955 Patent and this rejection should be withdrawn.

In addition, the Examiner has maintained the rejection of Claims 22-28 for double patenting over Claims 1-9 of U.S. Patent No. 5,217,876 (the "876 Patent"). Applicants respectfully request reconsideration and withdrawal of this rejection.

The Examiner maintains that Claims 22-28 are not patentably distinct from Claims 1-9 of the 876 Patent because "both inventions claim a device or instrument for detecting or monitoring the growth of microorganisms in a specimen comprising (a) a

container; (b) a filter or means for filtering; and a sensor means.” The Examiner further asserts that “[b]oth inventions require culturing of the microbial specimen before detecting or monitoring microbial growth with the device or instrument claimed.” The Examiner also asserts that “the structural features claimed in both inventions are substantially identical or describe minor variations deemed obvious to one having ordinary skill in this art at the time this invention was made.”

Applicants respectfully reassert that Claims 22-28 are patentably distinct from the claims of the 876 Patent. First, the claims of the 876 Patent do not provide for a device having a (1) an inlet and an outlet in fluid communication with the chamber as required by the present claims; and (2) a filter means as required by the present claims. The claims of the 876 Patent require the use of a sterile, specimen container. See the 876 Patent at column 8, lines 45-55. The container is further provided in the specification of the 876 Patent as being a sealed container. See the 876 Patent at column 1, lines 10-15 and column 2, lines 32-36. The container does not have any inlets or outlets for the specimen to flow into and out of the container, rather, the specimen is housed in the container for incubation. See the 876 Patent at column 8, lines 45-65.

The present invention, though, requires a container defining a chamber therein and having an inlet and an outlet in fluid communication with the chamber. See the present application at page 2, lines 9-11. A specimen is passed into the chamber through the inlet and out of the chamber through the outlet. See the present application at page 2, lines 14-16. The specimen is not housed nor cultured in the container.

With respect to the filter means required by the present claims, the Examiner asserted in the Office Action of October 1, 2003 that the invention of the 876 Patent selectively uses semi-permeable membranes or compositions which operatively filter the fluid sample and encompasses the instant invention as claimed. The semi-permeable membranes in the invention of the 796 Patent are a part of the sensor. See the 876 Patent at column 3, lines 52-55. Likewise, the present invention includes a sensor including semi-permeable membranes. The sensor in the invention in the 876 Patent and in the presently claimed device do not filter fluids, but rather, are used to determine the presence of microorganisms by detecting or measuring changes in the pH of the specimen or the production of CO₂ within the specimen. See the 876 patent at column 2, lines 36-41. The invention of the 876 Patent does not include a filter nor any component that filters fluids as required by the present claims.

Furthermore, it would not have been obvious to modify the invention of the 876 Patent to include an inlet, an outlet and a filter means as provided in the present invention since these components could not be operational in the invention claimed in the 876 Patent. The 876 Patent provides for monitoring pH or CO₂ changes in a specimen using a growth medium and a sealed container without entering the container after the sample is prepared and the container is sealed. See the 876 Patent at column 1, lines 11-15. Further, the claims of the 876 Patent require the specimen to be incubated with a growth medium and this medium enhances the production of certain microbial metabolic products. The monitoring process or incubation period for the specimen with the medium may last up to seven days before the population of organisms reaches a critical level or an increase in metabolic products can be measured. See the 876 Patent at column 3, line 66 through column 4, line 2.

The filter means of the present invention is mounted in the container between an inlet and an outlet at the end of the container opposite the sensor. The filter means filters fluids and collects the microorganisms as a specimen is passed into the inlet, through the filter means and out of the container through the outlet. If the inlet, outlet and filter means of the present invention were added to the container used in the methods of the 876 Patent, a specimen could not be cultured in the sterile culture medium as required in the claims of the 876 Patent because the microorganisms in the specimen would be caught by the filter when the specimen is added to the container and the specimen would be passed out of the container through the outlet. As such, the methods of the 876 Patent would not be operational as claimed if the inlet, outlet and filter means of the present invention were added to the container used in the methods of the 876 Patent. Therefore, it would not have been an obvious modification to add the inlet, outlet and filter means of the present invention to the container used in the methods of the 876 Patent.

Second, the invention of the 876 Patent and the present invention do not both require culturing of the microbial specimen in the device or instrument claimed as asserted by the Examiner. In the invention of the 876 Patent, a specimen is added to the container and the specimen is cultured in the container for up to 7 days. The claims of 876 Patent require that the specimen is cultured in the container. See the independent claims of the 796 Patent at column 8, line 45 through column 10, line 32.

However, the present invention does not require or provide for culturing the microbial specimen in the device claimed. Rather, when a specimen is added to the present device, the microorganisms are caught in the filter and then cultured. In particular, the

specimen is added to the presently claimed integrated device through the inlet, passed through the filter and out the device via the outlet. The microorganisms in the specimen are caught in the filter. The inlet and outlet can then be closed after a culture medium is added to culture the microorganisms caught in the filter. Accordingly, in the present invention, the specimen is not cultured in the container, rather only the microorganisms are cultured in the container whereas in the prior art, the whole specimen is cultured in the container.

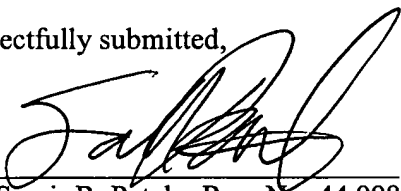
Accordingly, Applicants respectfully submit that pending Claims 22-28 are patentably distinct from the claims of the 876 Patent and this rejection should be withdrawn.

In view of the foregoing, it is respectfully submitted that the claims are in condition for allowance and prompt notice to that effect is earnestly solicited.

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Respectfully submitted,

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